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(54) Title: LARGE SCALE PREPARATION OF ALPHA-1 PROTEINASE INHIBITOR AND USE THEREOF

(57) Abstract: The present invention provides a process suitable for processing scaled-up amounts of source material in the range of tens of kilograms for the purification of alpha-1 proteinase inhibitor (API) from a mixture of unpurified proteins. More particularly, the present invention relates to a process for the purification of API from blood plasma or from plasma fractions to obtain pharmaceutical grade API on a commercial scale. The API produced by the process of the present invention is highly pure (at least 90% API out of the total protein) and highly active (at least 90% active API). The present invention also relates to pharmaceutical compositions comprising the purified API and methods of using same.

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